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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/071,713	02/07/2002	Adrian L. Faasse JR.	COR21 P-302	3238
7590	03/09/2005		EXAMINER	
Price, Heneveld, Cooper, DeWitt & Litton 695 Kenmoor, S.E. Post Office Box 2567 Grand Rapids, MI 49501			LEWIS, KIM M	
			ART UNIT	PAPER NUMBER
			3743	

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/071,713

Applicant(s)

FAASSE, ADRIAN L.

Examiner

Kim M. Lewis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2004 and 08 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10-34 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) 10-24 and 36-40 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 25-33 and 41 is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 7 and 34 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application (PTO-152)
- ☒ Other: Detailed Action.

DETAILED ACTION

Response to Amendment

1. The amendment filed on 12/13/04 has been received and made of record in the application file wrapper. As requested claims 1, 6 and 34 have been amended, claims 8, 9 and 35 have been canceled, and claim 41 has been added.
2. Claims 1-7, and 10-34 and 36-40 are pending, of which claims 10-24 and 36-40 have been withdrawn.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,628,724 ("DeBusk et al.").

As regards claim 1, DeBusk et al. anticipate the claimed invention. More specifically, DeBusk et al. disclose a wound dressing and delivery system comprising a polymeric film (layers 20 and 24), an adhesive coated surface comprising As regards claim 1, DeBusk et al. anticipate the claimed invention. More specifically, DeBusk et al. disclose a wound dressing and delivery system comprising a polymeric film (layers 20 and 24), a first adhesive (22) coated on a first side of the polymeric film, a handle (tab

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26) adhered by adhesive (28) to a second non-adhesive side of the polymeric film and a release liner (cover 42) covering the adhesive coated surface and extending beyond at least a first edge of the polymeric film.

The applicant should note that the first adhesive on the first side of the polymeric film adheres more aggressively to skin than the pressure sensitive adhesive adheres to the polymeric film in that the handle and layer (24) of the film layer can be removed from the polymeric film once the polymeric film is adhered to the skin of a patient (Figs. 5-7). If this were not the case, the pulling of tab (26) would also cause film layer (20) to be removed from the skin of the patient.

As regards claim 2, col. 3, lines 11-18 disclose the use of polyurethane film.

As regards claim 3, col. 5, line 3, disclose the use of a silicone coated release liner.

5. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,520,629 ("Heinecke et al.").

Regarding claim 34, as can be seen In Fig. 3, Heinecke et al. disclose a polymeric film backing (32) having a generally u-shaped handle (44) attached thereto to facilitate handling thereof, the handle includes spaced legs adhered to the film along opposite edges thereof, the handle includes a base portion joining the legs and being adhered along a third edge of said polymeric film layer (Fig. 4). The applicant should note the u-shaped handle is adhered to the backing via adhesive strips (46). Also, note

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that the handle of Heinecke et al. includes a handling tab, which is integral with the base (Figs. 3 and 4) and projects away from the base portion at the angled portions.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over DeBusk et al. in view of U.S. Patent No. 4,753,232 ("Ward").

As regards claim 4, DeBusk et al. fail to teach the adhesive is placed on the entire undersurface of the handle (tab 26). However, Ward discloses an adhesive wound dressing and various delivery systems therefor. The delivery systems of Ward include non-adhesive handles (Fig. 10), handles having adhesive over the entire

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undersurface (Fig. 2) and handles partially coated with adhesive (Fig. 5), depending upon the delivery method.

In view of Ward, it would have been obvious to one having ordinary skill in the art at the time the invention was made provide the handle (tab 26) of DeBusk et al. with adhesive on the entire undersurface thereof depending upon the delivery method.

9. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over DeBusk et al. in view of Heinecke et al.

As regards claims 6, DeBusk et al. fail to disclose a u-shaped handle. However, Heinecke et al. disclose an adhesive dressing and a delivery system therefor, wherein the delivery system comprises a u-shaped handle (44) as an alternate means for delivering the adhesive dressing. The handle includes spaced legs adhered to a film along opposite edges thereof, the handle includes a base portion joining the legs and being adhered along a third edge of said polymeric film layer (Fig. 3).

In view of Heinecke et al., it would have been obvious to one having ordinary skill in the art to modify the shape of the handle of DeBusk et al. to include a u-shaped handle as an alternate means for delivering the adhesive dressing.

As regards claim 7, note the handling tab, which is integral with the base in Fig. 4 of Heinecke et al.

Response to Arguments

The applicant argues that:

"[t]he DeBusk et al. patent does not teach or suggest a handle adhered to a second non-adhesive side of the polymeric film, but instead teaches a paper tab 26 adhered with an adhesive 28 to a carrier sheet 24. Further, the DeBusk et al. patent does not teach or suggest the requirement that the first adhesive (22 in the case of the DeBusk et al. patent) adhere more aggressively to the skin than the pressure sensitive adhesive (28 of DeBusk et al.) to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. To the contrary, the DeBusk et al. patent teaches that using the tab 26 as a handle, the carrier sheet 24 is lifted from the film dressing, "leaving the dressing 20 adhered to the wound site in a smooth unwrinkled disposition." (Column 5, lines 41-42). To anticipate a claim, the reference must teach every element of the claim. MPEP §2131. The DeBusk et al. patent does not teach a handle adhered to a second non-adhesive side of the polymeric film and does not teach the requirement for the first adhesive adhering more aggressively to the skin than the pressure sensitive adhesive to allow the handle to be removed from the polymeric film once the polymeric film is adhered to a patient's skin. Accordingly, claim 1 is in condition for allowance."

The examiner disagrees with this argument. First, applicant's attention is directed to the new rejection. Second, in order for the device of DeBusk et al. to operate as intended, the first adhesive must adhere more aggressively to the skin such that the handle can be removed from film layer (20) without pulling layer (20) from the skin of the patient.

In response to applicant's argument regarding claims 2 and 3, note the discussion above in response to the applicant's argument regarding claim 1.

In response to applicant's argument regarding claim 34, note the rejection above, which clearly points out how the examiner has determined that DeBusk et al. anticipates claim 34.

In response to applicant's argument regards claim 4, applicant's attention is directed to the rejection of claim 1, which more clearly points out how the DeBusk et al. patent anticipates the present invention.

As to the three criteria which must be present in order to establish a *prima facie* case of obviousness, the examiner contends that all three criteria have been met and are present in the rejection of claim 4 including motivation as to why one having ordinary skill in the art would have combined the teachings of DeBusk et al. and Ward to arrive at the present invention. It appears that the applicant primarily focuses on the supposed deficiencies of DeBusk et al. as they relate to independent claim 1. However, DeBusk et al. anticipate all features of independent claim 1 as articulated above.

In response to applicant's argument regarding claim 6 and 7, note the rejection above, which more clearly articulates the establishment of a *prima facie* case of obviousness. Additionally, applicant's argument that the references do not teach or suggest all of the claims limitations is incorrect since the examiner clearly addresses all of the claimed limitation in the rejections above.

Allowable Subject Matter

10. Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Claims 25-34 and 41 are allowed.

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12. The following is a statement of reasons for the indication of allowable subject matter:

The prior art fails to teach a dressing having a having handle that has an undersurface entirely coated with pressure sensitive adhesive, wherein the pressure sensitive adhesive does not adhere to the liner and does not adhere to skin.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

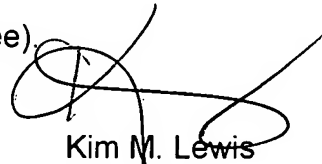
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kim M. Lewis whose telephone number is (571) 272-

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4796. The examiner can normally be reached on Mondays to Thursdays from 5:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry A. Bennett, can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kim M. Lewis
Primary Examiner
Art Unit 3743

kml
March 3, 2005